P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

K131884

510(k) Summary

Sponsor:

Zimmer, GmbH
Sulzer Allee 8
Winterthur
CH-8404
Switzerland

AUG 2 2 2013

Contact Person:

Karen O'Leary
Senior Specialist, Regulatory Affairs
Telephone: (574) 371-8515
Fax: (574) 372-4605

Date:

24 June 2013

Trade Name:

Avenir® Cemented Hip Stem

Common Name:

Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented

Classification Names and References:

21 CFR §888.3353 - LZO - Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented

21 CFR §888.3360 - LWJ - Prosthesis, hip, semi-constrained, metal/polymer, uncemented

21 CFR §888.3360 - KWL - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

21 CFR §888.3310 - KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer

21 CFR §888.3390 - KWY - prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented

Classification Panel:

Orthopedics/87

Predicate Device(s):

MS-30® Hip Prosthesis, manufactured by Zimmer GmbH,

- K993043, cleared December 2, 1999
- K001078, cleared June 23, 2000
- K020713, cleared May 14, 2002
- K040803, cleared April 29, 2004

Avenir® Müller Cementless Hip Stem, manufactured by Zimmer GmbH
- K123392, cleared March 4, 2013

Purpose and Device Description:

The *Avenir* Cemented Hip Stem is a femoral hip prosthesis that is designed for cemented fixation into the intramedullary canal for pathological or degenerative conditions involving the femur that merit total or hemi hip arthroplasty.

The *Avenir* Cemented Hip Stem is a straight, double-tapered stem manufactured from Protasul®- S30 stainless steel material. The tapered aspects of the stem match the *Avenir-Müller* Stem, and promotes self-locking of the stem within the femoral canal.

Intended Use:

The product is intended for total or hemi hip arthroplasty with cemented applications for rehabilitating hips damaged as a result of:

- Advanced wear of the joint due to degenerative, post-traumatic, or rheumatic diseases
- Failed previous hip surgery including joint reconstruction (osteotomy), arthrodesis, hemiarthroplasty or total hip replacement (THR)
- Acute traumatic fracture of the femoral head or neck
- Avascular necrosis of the femoral head.

Comparison to Predicate Device:

The *Avenir*® Cemented Stem is similar in intended use, materials, sterility and performance characteristics to the predicate device(s).

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical (lab) performance testing demonstrate the devices are safe and effective and substantially equivalent to the predicate devices. Performance testing/analysis included: Accelerated Corrosion Fatigue Test, Proximal & Mid-Stem Fatigue Testing, Pull-off Strength testing and rationale, summary of Burst Strength Testing and Range of Motion analysis.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Zimmer GmbH
Ms. Karen O'Leary
Senior Specialist, Regulatory Affairs
Zimmer Incorporated
P.O. Box 708
Warsaw, Indiana 46581

Re: K131884
Trade/Device Name: Avenir® Cemented Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, LWJ, KWL, KWZ, KWY
Dated: June 24, 2013
Received: June 25, 2013

Dear Ms. O'Leary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131884

Device Name:

Avenir® Cemented Hip Stem

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- Avascular necrosis of the femoral head.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices